

General

Guideline Title

Practice guideline update summary: botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: report of the Guideline Development Subcommittee of the American Academy of Neurology.

Bibliographic Source(s)

Simpson DM, Hallett M, Ashman EJ, Comella CL, Green MW, Gronseth GS, Armstrong MJ, Gloss D, Potrebic S, Jankovic J, Karp BP, Naumann M, So YT, Yablon SA. Practice guideline update summary: botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2016 May 10;86(19):1818-26. [40 references] [PubMed](#)

Guideline Status

This is the current release of the guideline.

This guideline updates previous versions:

- Simpson M, Gracies JM, Graham HK, et al; for the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Assessment: botulinum neurotoxin for the treatment of spasticity (an evidence-based review): report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology* 2008;70:1691–8.
- Simpson M, Blitzer A, Brashear A, et al; for the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Assessment: botulinum neurotoxin for the treatment of movement disorders (an evidence-based review): report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology* 2008;70:1699–706.
- Naumann M, So Y, Argoff CE, et al; for the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Assessment: botulinum toxin in the treatment of autonomic disorders and pain (an evidence-based review): report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology* 2008;70:1707–14.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Definitions of the levels of the recommendations (A, B, C, U) and classification of the evidence (Class I-IV) are provided at the end of the "Major Recommendations" field.

Blepharospasm

Recommendations

OnabotulinumtoxinA (onaBoNT-A) and incobotulinumtoxinA (incoBoNT-A) injections should be considered (Level B), and aboBoNT-A may be considered (Level C), as treatment options for blepharospasm.

Clinical Context

Botulinum neurotoxin (BoNT) is considered the first-line treatment of blepharospasm by most movement disorder specialists. All 3 type A toxins appear to have similar efficacy and can continue to be efficacious over long periods.

Cervical Dystonia (CD)

Recommendations

AbobotulinumtoxinA (aboBoNT-A) and rimabotulinumtoxinB (rimaBoNT-B) should be offered (Level A), and onaBoNT-A and incoBoNT-A should be considered (Level B), as options for the treatment of CD.

Clinical Context

BoNT is accepted as first-line treatment for CD. Although the evidence levels may differ across BoNT serotypes and brands, all formulations have regulatory approval and are commonly used. There is an extensive clinical history of onaBoNT-A and incoBoNT-A use, but the lack of additional Class I studies led to only a Level B recommendation. Comparative trials indicate similar efficacy for rimaBoNT-B and onaBoNT-A, and for aboBoNT-A and onaBoNT-A, in the treatment of CD.

Spasticity in Adults

Upper Extremity Spasticity

Recommendations

- For focal manifestations of adult spasticity involving the upper limb, aboBoNT-A, incoBoNT-A, and onaBoNT-A should be offered (Level A), and rimaBoNT-B should be considered (Level B), as treatment options.
- OnaBoNT-A should be considered as a treatment option before tizanidine (TZD) for treating adult upper extremity spasticity (Level B).
- Both high-volume, low-potency injections of onaBoNT-A and endplate targeting of onaBoNT-A into proximal upper extremity muscles should be considered to enhance tone reduction in spasticity (Level B).

Lower Extremity Spasticity

Recommendations

For focal manifestations of adult spasticity involving the lower limb that warrant treatment, onaBoNT-A and aboBoNT-A should be offered (Level A) as treatment options.

There is insufficient evidence to support or refute a benefit of incoBoNT-A or rimaBoNT-B for treatment of adult lower limb spasticity.

Clinical Context

Although BoNT can reduce increased tone in spasticity, the impact of BoNT injections on functional outcomes is mixed, suggesting that potential functional gains are highly patient-specific. Because of the lack of comparative trials, there is insufficient evidence to indicate that any one of the BoNT formulations is superior to the others.

Headache

Chronic Migraine (CM)

Recommendations

OnaBoNT-A should be offered as a treatment option to patients with CM to increase the number of headache-free days (Level A) and should be considered to reduce headache impact on health-related quality of life (QOL) (Level B).

Clinical Context

Although the reduction of headache days with onaBoNT-A was statistically superior to placebo in 2 Class I studies, the magnitude of the difference is small (1.7 and 2.3).

Episodic Migraine (EM)

Recommendation

OnaBoNT-A should not be offered as a treatment for EM (Level A).

Definitions

Therapeutic Classification of Evidence Scheme

Class I

A randomized, controlled clinical trial of the intervention of interest with masked or objective outcome assessment, in a representative population. Relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences.

The following are also required:

- a. Concealed allocation
- b. Primary outcome(s) clearly defined
- c. Exclusion/inclusion criteria clearly defined
- d. Adequate accounting for dropouts (with at least 80% of enrolled subjects completing the study) and crossovers with numbers sufficiently low to have minimal potential for bias
- e. For noninferiority or equivalence trials claiming to prove efficacy for one or both drugs, the following are also required*:
 1. The authors explicitly state the clinically meaningful difference to be excluded by defining the threshold for equivalence or noninferiority
 2. The standard treatment used in the study is substantially similar to that used in previous studies establishing efficacy of the standard treatment (e.g., for a drug, the mode of administration, dose, and dosage adjustments are similar to those previously shown to be effective)
 3. The inclusion and exclusion criteria for patient selection and the outcomes of patients on the standard treatment are comparable to those of previous studies establishing efficacy of the standard treatment
 4. The interpretation of the study results is based on a per-protocol analysis that accounts for dropouts or crossovers

Class II

A randomized, controlled clinical trial of the intervention of interest in a representative population with masked or objective outcome assessment that lacks one criteria a–e above or a prospective matched cohort study with masked or objective outcome assessment in a representative population that meets b–e above. Relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences.

Class III

All other controlled trials (including well-defined natural history controls or patients serving as own controls) in a representative population, where outcome is independently assessed, or independently derived by objective outcome measurement.**

Class IV

Studies not meeting Class I, II, or III criteria, including consensus or expert opinion.

*Numbers 1–3 in Class Ie are required for Class II in equivalence trials. If any one of the three is missing, the class is automatically downgraded to Class III.

**Objective outcome measurement: An outcome measure that is unlikely to be affected by an observer's (patient, treating physician, investigator) expectation or bias (e.g., blood tests, administrative outcome data).

Classification of Recommendations

A = Established as effective, ineffective or harmful (or established as useful/predictive or not useful/predictive) for the given condition in the specified population. (Level A rating requires at least two consistent Class I studies.)*

B = Probably effective, ineffective or harmful (or probably useful/predictive or not useful/predictive) for the given condition in the specified population. (Level B rating requires at least one Class I study or two consistent Class II studies.)

C = Possibly effective, ineffective or harmful (or possibly useful/predictive or not useful/predictive) for the given condition in the specified

population. (Level C rating requires at least one Class II study or two consistent Class III studies.)

U = Data inadequate or conflicting; given current knowledge, treatment (test, predictor) is unproven.

*In exceptional cases, one convincing Class I study may suffice for an "A" recommendation if 1) all criteria are met, 2) the magnitude of effect is large (relative rate improved outcome >5 and the lower limit of the confidence interval is >2).

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

- Blepharospasm
- Cervical dystonia (CD)
- Adult spasticity
- Headache

Guideline Category

Assessment of Therapeutic Effectiveness

Treatment

Clinical Specialty

Neurology

Intended Users

Physicians

Guideline Objective(s)

To update the 2008 American Academy of Neurology (AAN) guidelines regarding botulinum neurotoxin for blepharospasm, cervical dystonia (CD), headache, and adult spasticity

Target Population

Patients with blepharospasm, cervical dystonia (CD), adult spasticity, and headache

Interventions and Practices Considered

Botulinum neurotoxin (BoNT), including

1. AbobotulinumtoxinA (aboBoNT-A)
2. IncobotulinumtoxinA (incoBoNT-A)
3. OnabotulinumtoxinA (onaBoNT-A)

Major Outcomes Considered

- Headache-free days
- Range of motion
- Safety
- Quality of life (QOL)

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

The committee searched the EMBASE, Medline, and Science Citation Index databases to find relevant studies published from April 2007 (endpoint of the search performed for the prior guidelines) to August 2011. They updated the search in December 2014 and again in October 2015. The bibliographies of review articles also were searched to identify articles missed by the initial search strategy (see Appendix e-3 for complete search strategy). Additionally, because studies comparing different botulinum neurotoxin (BoNT) formulations in the treatment of cervical dystonia (CD) were not included in the 2008 guideline, they repeated the pre-2008 search to identify comparative trials.

To be eligible for inclusion, English-language articles had to compare outcomes between patients with blepharospasm, CD, adult spasticity, or headache receiving a preparation of BoNT that is commercially available in the United States with outcomes of a group of patients receiving an alternative therapy. Acceptable alternative therapies included placebo or another treatment—including a different form of BoNT or a different technique for administering BoNT. At least 20 patients must have been enrolled in each study. In general, only randomized, masked trials (RMTs) were considered. When RMTs were not available to assess long-term outcomes or safety concerns, evidence from nonrandomized trials was used.

Refer to Appendix e-3 in the supplement (see the "Availability of Companion Documents" field) for search terms.

The search identified 3,371 citations. A review of titles and abstracts identified 55 potentially relevant articles for blepharospasm, 100 for CD, 279 for spasticity, and 144 for headache. The committee reviewed the full text of these articles for meeting inclusion criteria.

Number of Source Documents

Twenty-three articles on blepharospasm, 23 on cervical dystonia (CD), 86 on spasticity, and 28 on headache met inclusion criteria. Table 2 in the original guideline document summarizes the conclusions from this review.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Therapeutic Classification of Evidence Scheme

Class I

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- a. Concealed allocation
- b. Primary outcome(s) clearly defined
- c. Exclusion/inclusion criteria clearly defined
- d. Adequate accounting for dropouts (with at least 80% of enrolled subjects completing the study) and crossovers with numbers sufficiently low to have minimal potential for bias
- e. For noninferiority or equivalence trials claiming to prove efficacy for one or both drugs, the following are also required*:
 1. The authors explicitly state the clinically meaningful difference to be excluded by defining the threshold for equivalence or noninferiority
 2. The standard treatment used in the study is substantially similar to that used in previous studies establishing efficacy of the standard treatment (e.g., for a drug, the mode of administration, dose, and dosage adjustments are similar to those previously shown to be effective)
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Class III

All other controlled trials (including well-defined natural history controls or patients serving as own controls) in a representative population, where outcome is independently assessed, or independently derived by objective outcome measurement.**

Class IV

Studies not meeting Class I, II, or III criteria, including consensus or expert opinion.

*Numbers 1–3 in Class Ie are required for Class II in equivalence trials. If any one of the three is missing the class is automatically downgraded to Class III.

**Objective outcome measurement: An outcome measure that is unlikely to be affected by an observer's (patient, treating physician, investigator) expectation or bias (e.g., blood tests, administrative outcome data).

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Each article was reviewed by at least 2 panelists who did not participate in or have a relevant conflict of interest with the reported trial. The panel classified each article for risk of bias (Class I, II, III, or IV) using the American Association of Neurology (AAN) classification scheme for therapeutic questions (see the "Rating Scheme for the Strength of the Evidence" field). Disagreements about article selection and classification were resolved by consensus.

Methods Used to Formulate the Recommendations

Description of Methods Used to Formulate the Recommendations

The panel formulated recommendations on the basis of the conclusions; recommendations are tied directly to the evidence (see Appendix e-5 in the Data Supplement [see "Availability of Companion Documents"]). Table e-1 (see Data Supplement in the "Availability of Companion Documents") presents the conclusions and recommendations for efficacy of various botulinum neurotoxin (BoNT) formulations.

Unlike the approach taken in previous American Academy of Neurology (AAN) guidelines, where BoNT was evaluated for safety and efficacy as a single class, in this update the panel assessed each formulation separately for each indication. As a result, the level of support for efficacy in the conclusions and recommendations may be lower for the individual BoNT formulations than it would be had BoNT been considered as a class. The recommendations reflect the confidence in the level of evidence, but because studies of comparative efficacy are few, the recommendations should not be construed to indicate that one drug is superior to another.

Rating Scheme for the Strength of the Recommendations

Classification of Recommendations

A = Established as effective, ineffective or harmful (or established as useful/predictive or not useful/predictive) for the given condition in the specified population. (Level A rating requires at least two consistent Class I studies.)*

B = Probably effective, ineffective or harmful (or probably useful/predictive or not useful/predictive) for the given condition in the specified population. (Level B rating requires at least one Class I study or two consistent Class II studies.)

C = Possibly effective, ineffective or harmful (or possibly useful/predictive or not useful/predictive) for the given condition in the specified population. (Level C rating requires at least one Class II study or two consistent Class III studies.)

U = Data inadequate or conflicting; given current knowledge, treatment (test, predictor) is unproven.

*In exceptional cases, one convincing Class I study may suffice for an "A" recommendation if 1) all criteria are met, 2) the magnitude of effect is large (relative rate improved outcome >5 and the lower limit of the confidence interval is >2).

Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Drafts of the guideline have been reviewed by at least 3 American Academy of Neurology (AAN) committees, a network of neurologists, *Neurology* peer reviewers, and representatives from related fields.

The guideline was approved by the Guideline Development Subcommittee on November 16, 2013; by the Practice Committee on February 27, 2015; and by the AAN Institute Board of Directors on January 19, 2016.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Improved health-related quality of life (QOL)
- Reduced caregiver burden
- Improved limb muscle function

Potential Harms

- Commonly reported adverse events (AEs) with botulinum neurotoxin (BoNT) injections included periorbital hematoma (25%), ptosis (range of risk differences [RDs] 13%–54%), dry eyes (range of RDs 7.1%–13%), and blurred vision (RD 42%).
- In a placebo-controlled study, rhinitis and treatment-related dysphagia were more frequent with onabotulinumtoxinA (onaBoNT-A).

Qualifying Statements

Qualifying Statements

The regulatory approved indications for botulinum neurotoxin (BoNT) do not necessarily correspond to those in the evidence-based recommendations presented in the guideline.

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Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Patient Resources

Quick Reference Guides/Physician Guides

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Safety

Identifying Information and Availability

Bibliographic Source(s)

Simpson DM, Hallett M, Ashman EJ, Comella CL, Green MW, Gronseth GS, Armstrong MJ, Gloss D, Potrebic S, Jankovic J, Karp BP, Naumann M, So YT, Yablon SA. Practice guideline update summary: botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2016 May 10;86(19):1818-26. [40 references] [PubMed](#)

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2016 May 10

Guideline Developer(s)

American Academy of Neurology - Medical Specialty Society

Source(s) of Funding

This guideline was developed with financial support from the American Academy of Neurology (AAN). Authors who serve as AAN subcommittee members or methodologists (E.J.A., G.S.G., M.J.A., D.G., S.P.) were reimbursed by the AAN for expenses related to travel to subcommittee meetings where drafts of manuscripts were reviewed.

Guideline Committee

Guideline Development Subcommittee of the American Academy of Neurology (AAN)

Composition of Group That Authored the Guideline

Guideline Authors: David M. Simpson, MD; Mark Hallett, MD; Eric J. Ashman, MD; Cynthia L. Comella, MD; Mark W. Green, MD; Gary S. Gronseth, MD; Melissa J. Armstrong, MD; David Gloss, MD; Sonja Potrebic, MD, PhD; Joseph Jankovic, MD; Barbara P. Karp, MD; Markus Naumann, MD; Yuen T. So, MD, PhD; Stuart A. Yablon, MD

2013–2015 Guideline Development Subcommittee (GDS) Members: Cynthia Harden, MD (*Chair*); Steven R. Messé, MD (*Vice-Chair*); Richard L. Barbano, MD, PhD; Jane Chan, MD; Diane Donley, MD; Terry Fife, MD; Jeffrey Fletcher, MD; Michael Haboubi, MD; John J. Halperin, MD; Cheryl Jaigobin, MD; Andres M. Kanner, MD; Jason Lazarou, MD; David Michelson, MD; Pushpa Narayanaswami, MD, MBBS; Maryam Oskoui, MD; Tamara Pringsheim, MD; Alexander Rae-Grant, MD; Kevin Sheth, MD; Kelly Sullivan, PhD; Theresa A. Zesiewicz, MD; Jonathan P. Hosey, MD (*Ex-Officio*); Stephen Ashwal, MD (*Ex-Officio*); Deborah Hirtz, MD (*Ex-Officio*); Jacqueline French, MD (*Ex-Officio*)

Financial Disclosures/Conflicts of Interest

Conflict of Interest

The American Academy of Neurology (AAN) is committed to producing independent, critical, and truthful clinical practice guidelines. Significant efforts are made to minimize the potential for conflicts of interest to influence the recommendations of this clinical practice guideline. To the extent possible, the AAN keeps separate those who have a financial stake in the success or failure of the products appraised in the CPGs and the developers of the guidelines. Conflict of interest forms were obtained from all authors and reviewed by an oversight committee prior to project initiation. AAN limits the participation of authors with substantial conflicts of interest. The AAN forbids commercial participation in, or funding of, guideline projects. The AAN Guideline Author Conflict of Interest Policy can be viewed at www.aan.com . For complete information on this process, access the 2004 AAN process manual.

Disclosure

D. Simpson has received research grants from and served as a consultant for Allergan Inc., Ipsen Ltd., Merz Pharmaceuticals, and Acorda Therapeutics. M. Hallett serves as a chair of the Neurotoxin Institute Advisory Council and has received research grants from Allergan Inc. and Merz Pharmaceuticals. E. Ashman served as a paid editor for *Neurology*® from 2011 to 2013. C. Comella has received research grants from and has served as a consultant for Allergan Inc., Ipsen Ltd., Merz Pharmaceuticals, and Revance Pharmaceuticals. M. Green and G. Gronseth report no disclosures relevant to the manuscript. M. Armstrong serves on the Level of Evidence Review Team for *Neurology* (not compensated financially) and serves as an evidence-based methodologist for the AAN. She has no conflicts of interest related to the topic of this guideline. D. Gloss and S. Potrebic report no disclosures relevant to the manuscript. J. Jankovic has received research grants from and served as a consultant for Allergan Inc., Ipsen Ltd., and Merz Pharmaceuticals. B. Karp has received a research grant from Allergan Inc. M. Naumann has served as a consultant for Allergan Inc. and Ipsen Ltd. Y. So reports no disclosures relevant to the manuscript. S. Yablon has served as a consultant for Allergan Inc., Ipsen Ltd., Medtronic Inc., and Merz Pharmaceuticals. Go to Neurology.org for full disclosures.

Guideline Endorser(s)

American Association of Neuromuscular and Electrodiagnostic Medicine - Medical Specialty Society

American Society of Plastic Surgeons - Medical Specialty Society

Guideline Status

This is the current release of the guideline.

This guideline updates previous versions:

- Simpson M, Gracies JM, Graham HK, et al; for the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Assessment: botulinum neurotoxin for the treatment of spasticity (an evidence-based review): report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology* 2008;70:1691–8.
- Simpson M, Blitzer A, Brashear A, et al; for the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Assessment: botulinum neurotoxin for the treatment of movement disorders (an evidence-based review): report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology* 2008;70:1699–706.
- Naumann M, So Y, Argoff CE, et al; for the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Assessment: botulinum toxin in the treatment of autonomic disorders and pain (an evidence-based review): report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology* 2008;70:1707–14.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

A list of American Academy of Neurology (AAN) guidelines, along with a link to this guideline, is available from the [AAN Web site](#)

Availability of Companion Documents

The following are available:

Practice guideline update summary: botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache. AAN summary of practice guideline update for clinicians. Minneapolis (MN): American Academy of Neurology; 2016. 3 p.

Available from the [American Academy of Neurology \(AAN\) Web site](#) .

Practice guideline update summary: botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache. Data supplement (article with e-appendices, e-tables, e-references). Minneapolis (MN): American Academy of Neurology; 2016. Available from the [Neurology Journal Web site](#) .

Practice guideline update summary: botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache. Video. Minneapolis (MN): American Academy of Neurology; 2016. Available from the [Neurology Journal Web site](#)

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Practice guideline update summary: botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache. Presentation slides. Minneapolis (MN): American Academy of Neurology; 2016. Available from the [AAN Web site](#)

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Barbano RL. Botulinum toxins in clinical practice. Gaps in knowledge. Guideline perspective. *Neurol Clin Pract*. 2016 Jun;6(3):206-8.

Available from the [Neurology Clinical Practice Web site](#) .

Govindarajan R, Shepard KM, Moschonas C, Chen JJ. Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache. Payment policy perspectives. Commentary. *Neurol Clin Pract*. 2016 Jun;6(3):281-6. Available from the

[Neurology Clinical Practice Web site](#) .

American Academy of Neurology (AAN). Clinical Practice Guideline Process Manual, 2011 Ed. St. Paul (MN): American Academy of Neurology. 2004. 57 p. Available from the [AAN Web site](#) .

Patient Resources

The following is available:

- Botulinum neurotoxin for treating blepharospasm, cervical dystonia, adult spasticity, and headache. AAN summary of practice guideline update for patients and their families. Minneapolis (MN): American Academy of Neurology (AAN). 2016. 3 p. Available from the [American Academy of Neurology \(AAN\) Web site](#) .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on October 31, 2008. The information was verified by the guideline developer on December 30, 2008. This summary was updated by ECRI Institute on May 26, 2009, following the U.S. Food and Drug Administration advisory on Botox, Botox Cosmetic (Botulinum toxin Type A), and Myobloc (Botulinum toxin Type B). This summary was updated by ECRI Institute on August 17, 2009, following the updated FDA advisory on Botox and Botox Cosmetic (Botulinum toxin Type A), and Myobloc (Botulinum toxin Type B). This summary was updated by ECRI Institute on June 26, 2016. The updated information was verified by the guideline developer on June 28, 2016.

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